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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,818	12/21/2001	Mitsuhiro Nakamura	217323US0PCT	4756

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EXAMINER

SAUCIER, SANDRA E

ART UNIT PAPER NUMBER

1651

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/926,818

Applicant(s)
Nakamura et al.

Examiner
Sandra Saucier

Art Unit
1651



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 14, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above, claim(s) 8-35, 41, and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 36-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Dec 21, 2002 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3, 1, 8 6) ☐ Other:

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DETAILED ACTION

Claims 1–42 are pending. Claims 1–7, 36–40 are considered on the merits. Claims 8–35, 41, 42 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claims 8–35, 41, 42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected, the requirement having been traversed in Paper No. 10.

The traversal is on the grounds that a) the groups share a common technical feature, namely the enzyme that acts on free cholesterol and that b) a different standard has been applied because the groups were not restricted in the examination of the PCT application.

Applicants appear to urge that cholesterol oxidase or cholesterol dehydrogenase is the common technical feature which links the groups. However, the groups must share a special technical feature which is a feature that is a contribution over the prior art, PCT Rule 13.2. Thus a feature found in the prior art cannot be considered to be a special technical feature which would link groups. As cholesterol oxidase and cholesterol dehydrogenase are both well known enzymes, they cannot be considered to be a special technical feature. The argument is unpersuasive because no special technical feature as urged exists to link the groups.

Applicants also argue that all groups have been examined together in the PCT application and that a different standard has been applied. There is no rule which states that if the groups are not restricted in the PCT application, they cannot be restricted in the 371 filing, as long as the restriction is properly formulated. Thus, this argument is without merit.

Claim Rejections – 35 USC § 101

Claims 2, 5, 36, 37 and 40 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

Careful analysis of the data presented in Table 5 shows

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that the values obtained with the addition of 1 U/ml cholesterol oxidase (A) versus the values obtained with the addition of 5 U/ml cholesterol oxidase (Standard) are the same or even larger values for 12 out of 25 samples tested.

Given the variation inherent in the determinations, the alleged decrease in the value obtained when the concentration of cholesterol oxidase is decreased from 5 to 1 U/ml does not appear to be statistically significant. Thus, the first premise of the inventors appears to be flawed. However, for the sake of argument, the analysis is continued below.

Applicants then allege that the addition of the "accelerator" (B-I) to the reaction mixture makes it possible to decrease the amount of cholesterol oxidase that is used, while obtaining the same value as if more cholesterol oxidase were used. Thus, the 13/25 Samples where a decrease in the value is observed when cholesterol oxidase is 1U/ml (A) versus 5 U/ml (Standard), should have a value in columns B-I which is higher than when 1 U/ml cholesterol oxidase is used alone (A).

Examination of the data does not demonstrate such a correlation.

Sample 1, C is lower or the same as A,

Sample 2, C, E are lower or the same as A

Sample 3, C,E,F,G are lower or the same as A

Sample 4, B,C,D,E,F,G,H are lower or the same as A

Sample 5 shows no effect on the values obtained using either 5 or 1 U/ml cholesterol oxidase and thus cannot be used to support the allegation of "acceleration" since there is no lowering of the value due to use of less oxidase and in fact could be used to show an inhibitory effect of the "accelerants".

Sample 6, C, F are lower or the same as A,

Sample 7, C are lower or the same as A,

Samples 8 and 9, show no effect on the values obtained using either 5 or 1 U/ml cholesterol oxidase and in fact could be used to show an inhibitory effect of the "accelerants".

Sample 10, C, E, F, G, I are lower or the same as A,

Sample 11, C, E are lower or the same as A,

Sample 12, B, C, D, E, F, G, I are lower or the same as A,

Sample 13, C,D,E,F,G,H,I are lower or the same as A,

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Sample 14 shows no effect on the values obtained using either 5 or 1 U/ml cholesterol oxidase and in fact could be used to show an inhibitory effect of the "accelerants".

Sample 15, B,C,D,E,F,G,H,I are lower or the same as A,

Sample 16, B,C,D,E,F,G,H,I are lower or the same as A,

Sample 17, B,C,D,E,F,G,H are lower or the same as A,

Samples 18,19, 20, 21, 22, 23, 24, 25 show no effect on the values obtained using either 5 or 1 U/ml cholesterol oxidase and in fact could be used to show an inhibitory effect of the "accelerants".

Out of the 13 samples which have a decrease in values obtained when the cholesterol oxidase concentration is decreased from 5 to 1U/ml, namely samples 1-4, 6, 7, 10-13, 15-17, using the eight "accelerators" B-I, which is a total of $13 \times 8 = 104$ data points, only 42 data points support the assertion that the compounds are "accelerators", that is, the value of each of these 42 are greater than A, while the other 62 contradict this assertion, that is the values of each of these 62 is less or equal to A. Further, no single "accelerant" consistently "accelerates" or increases the value to that obtained when 5U/ml cholesterol oxidase is used. In fact, for example, "accelerant C never increases the value. The data appears to be only random variation, and does not display a significant or consistent effect. Therefore, there does not appear to be a useful invention in the addition of "accelerators" to assays for the determination of cholesterol concentrations.

Applicants' own data does not support the utility of the claimed invention.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 1-7, 36-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The cholesterol is not "consumed" that is reduced to hydrogen, carbon and oxygen, by cholesterol oxidase or dehydrogenase it is merely converted to a different sterol.

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Claims 36 and 37 are indefinite because they are incomplete in that no sample is mentioned upon which the enzyme "acts" and no quantitating step is seen which is mentioned in the preambles. It is unclear if the enzyme and the accelerator are present together in a sample. "Free cholesterol" appears to mean cholesterol which is not esterified in the 3-hydroxy position however, what does "total" cholesterol mean when a sample is not specified as in claim 37.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3, 4, 6, 7 and 38 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by JP 11-155595 [N].

The claims are directed to a one step method for treating a sample containing lipoproteins comprising:
causing an enzyme which acts upon free cholesterol to act on the sample to "consume" the free cholesterol, whereby the lipoproteins remain substantially unchanged.

The references are relied upon as explained below.

JP 11-155595 discloses a method of assaying cholesterol in a sample containing various lipoproteins comprising first treating the sample with cholesterol oxidase.

This is the same sample as is treated in the instant claims and is the same one step method of causing an enzyme which acts upon free cholesterol as a substrate to act upon the sample to "consume" the free cholesterol.

Because the sample is the same and the one active step of "causing an enzyme which acts upon free cholesterol to act upon the sample" is the same, the result, which is "the lipoproteins remain unchanged" is reasonably considered to also be the same result in the absence of evidence to the contrary.

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See example 2 where cholesterol oxidase (1-B) is added to serum in a determination of HDL cholesterol concentration.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized flourish at the end.

Sandra Saucier
Primary Examiner
Art Unit 1651
April 15, 2003